

## INTRODUCTION

The present Request was issued after the Applicant had filed an Appeal Brief on August 14, 2008, and after a response to a previous Request for Information Under 37 CFR §1.105, was filed on March 14, 2006, which included copies of multiple abstracts and 360 printed slides.

The present Request acknowledges receipt of the Appeal Brief filed on August 14, 2008, but states that "... after further review of the application it was determined that additional information was required before prosecution can proceed." However, the present Request does not indicate if the prosecution has been reopened, and this was confirmed by Examiner Angell in a telephone discussion on November 18, 2008.

## DISCUSSION

### A. The Present Request for Information is Late or Untimely

The MPEP §704.11(b) states that "[o]rdinarily, a request for information should not be made with or after a final rejection." (Emphasis added).

Further, the MPEP §704.11(b) III elaborates:

A requirement for information is not proper when no further action will be taken by the examiner. The reasonable necessity criteria for a requirement for information implies further action by the examiner. This means that actions in which requirements for information **necessary for examination** are made should generally be a non-final action because the applicant's reply must be considered and applied as appropriate. (Emphasis added).

As noted above, the present Request was issued after filing of an Appeal Brief by the Applicant and the prosecution has not been reopened. Therefore, it does not appear that any further action is to be taken by the Examiner, other than to furnish a written answer to the Applicant's appeal brief, and no indication is made that the requested information is necessary for examination. Accordingly, it is respectfully submitted that the present Request for information is late or untimely, and thus improper.

B. The Type of Information Sought by the Present Request for Information Does Not Appear to Fit Into Any of the Enumerated Categories

37 CFR §1.105(a)(1)(i) lists specific examples of information that may reasonably be required. Other examples, not meant to be exhaustive, are provided at MPEP §704.11(a).

It is respectfully submitted that the type of the information required by the present Request does not seem to fit any of the examples listed in Rule 105, or additional examples listed in the MPEP, other than *arguably* the catchall category, provided at the MPEP §704.11(a)(P) directed to "other factual information..." (Emphasis added). However, as noted below, the present Request does not seem to be directed to seeking legally relevant factual information.

C. The Present Request for Information Does Not Meet the Criteria of Reasonable Necessity

The present Request for information merely states that the requested information is “reasonably necessary to determine if the claim insulated regular construct(s) was publicly disclosed prior to the filing of the instant application,” without providing any reasoning therefor.

The MPEP §704.11 states:

There must be a reasonable basis for the information required that would aid in the examination of an application or treatment of some matter. A requirement for information under 37 CFR 1.105 places a substantial burden on the applicant that is to be minimized by clearly focusing the reason for the requirement and the scope of the expected response. Thus, the scope of the requirement should be narrowly defined, and a requirement under 37 CFR 1.105 may only be made when the examiner has a reasonable basis for requiring information. (Emphasis added).

The MPEP §704.14(a) further requires that a request for information must clearly indicate “... the basis for the requirement...” (Emphasis added). In order to explain the criteria of reasonable necessity, the MPEP provides two instances (see §704.11, at page 700-8, left column).

The first instance deals with a situation where the invention as a whole is in a new area of technology or has a class with a few pieces of art. The second instance deals with the situation where "a more complete understanding of the invention and its context" is needed. It is submitted that neither of these instances seem to apply to the present application.

The present Request for information states that:

Although Applicants have submitted the information requested regarding the presentations, after reviewing the submitted information, a basic question still remains: is the insulin regulator construct disclosed in the abstracts and presentations the same insulin construct that is now claimed? (Emphasis added).

The present Request for information further states that:

The information that is required is an indication of whether or not the claimed insulin regulator construct(s) are the same constructs that were disclosed in abstracts and presentations given by Applicant prior to filing of the instant application,...."

From the above, it appears that the Examiner is requesting not the factual information, but an opinion. It is submitted that all the "facts" and "factual"<sup>1</sup> information regarding the various presentations given by the Applicant, as noted in the present Request, and other public disclosures, were submitted earlier on March 14, 2006, in

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<sup>1</sup> "The terms "factual" and "facts" are included in 37 CFR 1.105 to make it clear that it is facts and factual information ...that are sought...." MPEP §704.11, 3<sup>rd</sup> paragraph, at 700-7 (emphasis added).

response to the previous Request for Information. In seeking the Applicant's knowledge or conclusion of what was disclosed in the abstracts and the presentations, the Examiner is improperly relying on the subjective knowledge of the inventor, than the objective facts that would have been available to one of ordinary skill in the art. To inject the inventor's knowledge into an equation to determine patentability, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 851 (1984).

Therefore, it is respectfully submitted that the criteria of reasonable necessity and, therefore, the basis for the requirement, has not been properly established, or met under the rules.

#### THE REQUESTED INFORMATION

The above notwithstanding, the present Request for Information is being understood by the Applicant as a request to supply factual information to aid in prosecution, and not as a request to have the Applicant reach a conclusion of law. Consistent with this understanding and without any admission of anticipation of pending Claims 1-15 under 35 U.S.C. §102(b) over the references set forth in the Final Rejection of December 12, 2007, Applicant notes that while the claimed construct(s) of Claim 9 is the same as that generally referred to in the abstracts and presentations, the sequences recited in Claim 9 were not disclosed in the abstracts and presentations.